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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/622,487

08/17/2000

Shuji Sumida

0263-4047

7215

7590

05/29/2002

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/29/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/622,487

Applicant(s)

SUMIDA ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7, 8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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1. The rejections set forth in the previous Office action are withdrawn in view of the amendments made to the claims and in view of the arguments set forth in the response filed February 25, 2002.

2. Claims 1, 7, 8, and 10-12 are objected to because of the following informalities: At claim 1, line 3, "and" should be changed to "an". Appropriate correction is required.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 7, 8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuji et al (U.S. Patent No. 5,202,117) in view of Michaelis et al (U.S. Patent No. 5,919,757). Tsuji et al teach an aqueous solution comprising equal amounts by weight of Polysorbate 80, a nonionic surfactant, and human G-CSF. The pH of the solution is 7. The solution is free from protein as a stabilizer. The solution is packaged in a vial. See column 8, line 56 - column 9, line 2. The source of the human G-CSF in Example 2 of Tsuji et al is Referential Example 2, in which recombinant G-CSF is produced by recombinant gene technology from transformed CHO cells (see column 5, lines 8-11 and 40-58). Michaelis et al teach that G-CSF produced in CHO cells is glycosylated (see column 2, lines 39-42).

5. Claims 3-5, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over Tsuji et al (U.S. Patent No. 5,202,117) in view of Michaelis et al (U.S. Patent No. 5,919,757).

Application of the references is the same as in the above rejection of claims 1, 2, 7, 8, and 12.

Tsuji et al do not teach the weight ratios and pHs recited in instant claims 3-5, 10, and 11. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal weight ratios and pHs for the compositions of the

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Tsuji et al because weight ratio and pH are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical composition arts. The disclosure of Tsuji et al is not limited to any particular weight ratios or pHs, and slight deviations from the particular weight ratios and pHs disclosed in the examples of Tsuji et al does not impart patentability to composition claims in the absence of evidence of unexpected results.

6. Claims 1-5, 7, 8, and 10-12 are rejected under 35 U.S.C. 103(a) as being obvious over the Japanese Patent Application 4-77436. (Citations in the rejection will be to the translation of the reference provided herein.) The Japanese Patent Application '436 teaches an aqueous solution comprising equal amounts by weight of Polysorbate 80, a nonionic surfactant, and human G-CSF. The pH of the solution is 7. The solution is free from protein as a stabilizer. The solution is packaged in a vial. See page 10, Practical Example 2. The Japanese Patent Application '436 does not teach the use of glycosylated human G-CSF in this solution, although the Japanese Patent Application '436 at page 5, lines 5-19, does teach glycoproteins comprising human G-CSF and a sugar chain to be preferred human G-CSF. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form a solution according to Practical Example 2 of the Japanese Patent Application '436 using a glycoprotein comprising human G-CSF and a sugar chain as the source of the human G-CSF because it is desirable to be able to prepare and store for use all known pharmaceutically active agents and because the Japanese Patent Application '436 teaches that a glycoprotein comprising human G-CSF and a sugar chain is a preferred source of the human G-CSF for the disclosed invention. With respect to instant claims 3-5, 10, and 11, practical Example 2 of the Japanese Patent Application '436 differs from these claims in the ratio of surfactant to G-CSF and in pH.

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However, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal weight ratios and pHs for the compositions of the Japanese Patent Application '436 because weight ratio and pH are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical composition arts. The disclosure of the Japanese Patent Application '436 is not limited to any particular weight ratios or pHs, and slight deviations from the particular weight ratios and pHs disclosed in the examples of the Japanese Patent Application '436 does not impart patentability to composition claims in the absence of evidence of unexpected results.

5. Applicant's arguments filed February 25, 2002 have been fully considered but they are not persuasive.

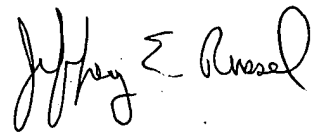
Tsuji et al are deemed to be closer than Michaelis et al (U.S. Patent 5,919,757) to the instant claimed invention because Tsuji et al teach glycosylated human G-CSF. The Japanese Patent Application 4-77436 is deemed to be closer than Michaelis et al (U.S. Patent 5,919,757) to the instant claimed invention because the Japanese Patent Application '436 teaches glycosylated human G-CSF to be a preferred source of human G-CS. Note that each of the three references teaches the combination of solutions free of protein stabilizer, having a pH=7, and with equal or lesser amount of nonionic surfactant than G-CSF on a weight basis (see Table 4a of Michaelis et al '757). The prior art need not use the same descriptive terminology chosen by Applicants, i.e. the prior art need not label polysorbate as a stabilizer, in order to teach or suggest the claimed invention. See *In re Skoner*, 186 USPQ 80, 82 (CCPA 1975).

The Japanese Patent Application 5-339164 is cited as art of interest, being essentially duplicative of the references applied or discussed above.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

May 28, 2002